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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,447	06/24/2003	Erik Ho Fong Wong	00054.US1	9394

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PHARMACIA & UPJOHN
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EXAMINER

CLAYTOR, DEIRDRE RENEE

ART UNIT	PAPER NUMBER
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1617

MAIL DATE	DELIVERY MODE
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05/02/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/602,447

Applicant(s)

WONG, ERIK HO FONG

Examiner

Renee Claytor

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-9,11,12,14-31 and 33-53 is/are pending in the application.
- 4a) Of the above claim(s) 1,4-9,11,12,14-30,33 and 36-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31 and 34-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| <p>1) <input type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.</p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application</p> <p>6) <input type="checkbox"/> Other: _____.</p> |
|---|--|

DETAILED ACTION

Applicant's arguments with respect to claims 31 and 34-35 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31 and 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harkin et al. (European Journal of Pharmacology 364 (1999) 123-32) in view of Wong et al. (U.S. Patent 6,465,458).

Harkin et al. teach a combination of the pharmaceutical agents reboxetine and sertraline used in a method for treating depression (meeting the limitations of claims 31 and 34-35; page 124, last paragraph of Introduction). It is further described in study 2 that reboxetine and sertraline were dissolved in distilled water (pg. 126, second paragraph under section 2.9).

Harkin et al. do not teach the S,S-enantiomer of reboxetine.

Wong et al. teach a pharmaceutical composition comprised of the S,S-enantiomer of reboxetine (Col. 5, lines 35-39).

Accordingly, it would be obvious to one having ordinary skill in the art at the time of the invention to combine the teachings of Harkin et al, which teaches a composition

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comprised of reboxetine and sertraline, with the teachings of Wong et al. which teaches the use of the S,S-enantiomer of reboxetine in a pharmaceutical composition. One would be motivated to utilize the S,S-enantiomer of reboxetine in the composition of Harkin et al. because Wong et al. teaches that the S,S-enantiomer of reboxetine does not have the adverse side effect profile associated with the racemic mixture (see Col. 6, lines 44-52).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 31 and 34-35 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6-9 and 11-19

of copending Application No. 10/769,018. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are drawn to a pharmaceutical composition comprised of S,S-reboxetine and an agent selected from antidepressants (sertraline). The claims of Application No. 10/769,018 are drawn to pharmaceutical compositions comprised of a serotonin reuptake inhibitor (sertraline) and a norepinephrine reuptake inhibitor (reboxetine). Application No. 10/759,018 makes not mention of the enantiomeric form of the sertraline/reboxetine mixture; however, it would be obvious to person of ordinary skill in the art at the time of the invention to use any enantiomeric form of reboxetine to combine with sertraline in an effort to formulate a composition that is comprised of sertraline and reboxetine to treat a condition or disease.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 31 and 34-35 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 59, 62-63, 65-67, 69-73 of copending Application No. 10/860,721. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are drawn to a pharmaceutical composition comprised of S,S-reboxetine and an agent selected from antidepressants (sertraline). The claims of Application No. 10/860,721 are drawn to compositions comprised of a serotonin reuptake inhibitor (sertraline) and a norepinephrine reuptake inhibitor (S,S-reboxetine).

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The claims differ in that the claims of Application No. 10/860,721 further include dose ranges of the agents; therefore, it would be obvious to one of ordinary skill in the art to optimize the dose range of the claimed composition in an effort to find a dose range to effectively treat a disease or condition.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Contact Information


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is 571-272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER